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Automated tracheal intubation in an airway manikin using a robotic endoscope: a proof of concept study

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Abstract: Robotic endoscope-automated via laryngeal imaging for tracheal intubation (REALTI) has been developed to enable automated tracheal intubation. This proof-of-concept study using a convenience sample of participants, comprised of trained anaesthetists and lay participants with no medical training, assessed the performance of a robotic device for the insertion of a tracheal tube into a manikin. A prototype robotic endoscope device was inserted into the trachea of an airway manikin by seven anaesthetists and seven participants with no medical training. Each individual performed six device insertions into the trachea in manual mode and six in automated mode. The anaesthetists succeeded with 40/42 (95%) manual insertions (median (IQR [range]) 17 (12-26 [4-132]) s) and 40/42 (95%) automated insertions (15 (13-18 [7-25]) s). The non-trained participants succeeded in 41/42 (98%) manual insertions (median (IQR [range]) 18 (13-21 [8-133]) s) and 42/42 (100%) automated insertions (16 (13-23 [10-58])] s). The duration of insertion did not differ between groups. An effect of increasing experience was observed in both groups in manual mode. A Likert scale for 'ease of use' (0 = very difficult to 10 = very easy) showed similar results within the two groups; the mean (SD) was 5.9 (2.1) for the anaesthetists and 6.9 (1.3) for the non-trained participants. We have successfully performed the first automated tracheal device insertion in a manikin with comparable results in a convenience sample of anaesthetists and lay participants with no medical training.

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Automated tracheal intubation in an airway manikin using a robotic endoscope. A proof of concept study

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Keywords

Airway management, tracheal intubation, automated intubation, robotic intubation, robotic endoscope

Summary

Robotic endoscope-automated via laryngeal imaging for tracheal intubation has been developed to enable automated tracheal intubation. This proof-of-concept study using a convenience sample of participants compared performance of the robotic device for insertion of a tracheal tube into a manikin performed by trained anaesthetists compared with subjects with no medical training. A prototype robotic endoscope device was inserted into the trachea of an airway manikin by seven anaesthetists and seven subjects with no medical training. Each individual performed six device insertions into the trachea in manual and six in automated mode. The anaesthetists succeeded with 40/42 (95%) manual insertions (median (IQR [range]) 17 (12-26 [4-132]) seconds) and 40/42 (95%) automated insertions (15 (13-18[7-25]) seconds). The non-trained subjects succeeded in 41/42 (98%) manual insertions (median (IQR [range]) 18 (13-21 [8-133]) seconds) and 42/42 (100%) automated insertions (16 (13-23 [10-58])] seconds). Duration of insertion did not differ between groups. An effect of increasing experience was observed in both groups in manual mode. A Likert scale for 'ease of use' (0=very difficult to 10=very easy) was similar between the two groups; mean (SD) 5.9 (2.1) for anaesthetists and 6.9 (1.3) for non-trained subjects. We have successfully performed the first automated tracheal device insertion in a manikin with comparable results in a convenience sample of anaesthetists compared with subjects with no medical training.

Introduction

The acronym REALITI, 'robotic endoscope-automated via laryngeal imaging for tracheal intubation', is a video-endoscopic stylet that guides a tracheal tube, mounted over its shaft, into the trachea. The bending motion of the endoscope tip can either be controlled manually or, upon demand, bends automatically towards the glottic entrance.

The inability to perform tracheal intubation and/or misplacement of the tracheal tube can result in asphyxia, hypoxemia, and pulmonary aspiration potentially leading to severe morbidity and mortality [1]. In emergency situations, the necessity to perform tracheal intubation may occur unexpectedly, infrequently, and under unfavourable conditions. [2-5] Tracheal intubation under these circumstances has a lower first-pass success rate and increased complication profile. [6,7] In contrast, in the operating room environment with experienced anaesthetists under elective conditions, the success rate of tracheal intubation much higher. [8] Recent alternative techniques to overcome the difficulties of tracheal intubation procedures are based on a visibly guided approach either by flexible endoscopes or videolaryngoscopy. These newer techniques allow the user to visualise the glottic entrance when direct laryngoscopy fails. However, visualizing the glottic inlet doesn't always translate to the ability to place a tracheal tube into the trachea.

By using the capacity of REALITI for image recognition and automated distal tip orientation, we compared the performance of device insertion into a manikin trachea by experienced anaesthetists versus participants with no medical training. This investigation is a first "proof of concept" for this approach with a pre-clinical prototype of REALITI in a simulated environment.

The REALITI prototype used in this study has a rigid shaft, a distal articulated section, and at its tip a light source and a camera (Figures 1,2). The shaft acts as a guide for the tracheal tube. The handle contains a microprocessor and the actuation unit that steers the articulated section. The axial movement in or out of the airway is manual only and independent from the (manual or automated) steering mode of the terminal articulated section.

In manual mode, the slow and steady forwarding of the endoscope into the oro-pharynx is done with a slight sagittal upward trajectory. During this procedure, the user manipulates the joystick according to the camera image to control the bending motion of the distil articulated section within two orthogonal directions. By combination of the two orthogonal directions, the articulated section is able to bend into all directions up to 90° without necessitating an axial rotation of the shaft. When the image recognition detects a familiar structure (e.g. the glottic opening), a square appears on the screen around it. The user then can activate the automated mode by pushing and holding a dedicated button. The automated mode moves the tip in the direction of the geometrical centre point of the glottic opening. Image recognition occurs when anatomic components of the glottis enter into the viewing angle of the tip camera, and correspond or strongly resemble saved images stored in the electronic data base. Anatomical features are automatically detected by the camera and recognized (Figure 1).

Once the vocal cords have been passed, the tracheal lumen is visually confirmed by the user. Of note, although the REALITI system is designed to railroad a mounted tracheal tube into the airway, in this study we refrained from this final phase of tracheal intubation and considered the forwarding of the endoscope tip as a sufficient end-point to determine the functionality of the device. In the manikin, due to the stiffness of the material, the concomitant use of direct laryngoscopy is not required. In humans, concomitant use of direct laryngoscopy is required to create enough space to visualize the anatomical structures.

Methods

The local Research Ethics Committee determined our proof of concept study did not require ethics approval. The pre-clinical REALITI prototype was configured to recognise the upper airway anatomy of the Airway Management Training Manikin (Laerdal Medical AS, Stavanger, Norway), used in this simulation trial. Based on convenience and availability, we invited 14 subjects with no previous knowledge of the REALITI system to perform tracheal device insertions in a manikin. Seven participants were clinically experienced employees of the Institute of Anaesthesiology at the University Hospital Zurich, Switzerland (4 physicians and 3 nurse anaesthetists). Seven other subjects with no medical training were also recruited (engineering students and personnel of the Multi-Scale Robotics Lab) at the Swiss Federal Institute of Technology (ETH) Zurich, Switzerland.

All participants gave their written consent to the anonymous use of their data and completed a questionnaire about their personal experience in airway management and the use of joystick-controlled devices.

All participants received instruction on the properties and functions of REALITI. All were able to inspect and practice with REALITI in both manual and automated modes prior to use in the manikin. Group N received additional education about upper airway anatomy. Group N was shown images of the hypopharynx, larynx, oesophagus and trachea when viewed on the video screen of an endoscope. This teaching lasted approximately five-minutes and was accompanied by explanations from the investigator (PB).

All participants performed two pre-study device insertions into the manikin trachea to familiarise themselves with both the device and the manikin. Once these steps were completed, the measured trials were performed consecutively, beginning with six instrument insertions in manual mode, followed immediately by six insertions in automated mode. Manual mode was performed first by all participants because of the desired potential training effect afforded in manual mode. In both modes, a direct laryngoscope was inserted by the participant prior to insertion of the REALITI device. Simultaneous use of direct laryngoscopy allows for hypopharyngeal space around the REALITI device. In addition, although the REALITI device is meant to act as a stylet for an endotracheal tube, in order to study REALITI use on its own, endotracheal tube insertion was not a component of this study.

In manual mode, the user steered the endoscope with the joystick, while slowly forwarding it into the oral cavity which was kept open by the previously inserted direct laryngoscope. In automated mode, as soon as the first anatomical landmarks were recognised by the system the user was encouraged to press the button to engage the automated mode. Recognition of anatomic landmarks was indicated by the appearance of squares around the identified features (Figures 1). To obtain consistent operating conditions, the manikin was placed in a standard position (Figure 2).

The assessment parameters included participant demographic details and any pre-existing experience with airway management, including tracheal intubation with direct laryngoscopy and/or flexible endoscopes. Primary outcome was time taken from insertion of the tip of REALITI device into the mankin mouth to visualizing tracheal rings on the video screen. Failure of insertion of the device was defined as the inability to insert the device in less than 180 seconds. After completing the 12 consecutive instrument insertions, the participants were asked about “ease of use” of REALITI using a Likert scale from 0 (very difficult) to 10 (very easy).

Data were subjected to comparative assessments between the two groups and the two operating modes. Descriptive statistics included means, standard deviations, medians and interquartile ranges for continuous data and proportions for categorical data. A Mann-Whitney test was used to compare the answers of the Likert scale assessing ease of use questionnaire. To compare instrument insertion times and account for several instrument insertions performed sequentially by the same participant, a linear mixed model with random intercept for each participant was calculated as measurements were not independent. This model was adjusted for manual versus automatic mode of the REALITI (binary variable: yes/no), previous experience with handling a joystick (binary variable: yes/no), familiarity with flexible endoscopes (binary variable: yes/no) and an interaction term between group and mode.

In addition, two separate models with stratification by manual and automated mode were analysed. In these models we included an interaction between the group and a variable representing the order of the tracheal intubations performed to quantify the effect of increasing experience. The residuals of all models were checked for approximate normal distribution. In a sensitivity analysis, we recalculated all models where the intubation times were transformed using the natural logarithm. All analyses were performed with R, version 3.5.3.

Results

Baseline characteristics of the study subjects are shown in Table 1. A total number of 168 tracheal device insertions were initially planned, but due to a transitory malfunction of the device, five attempts were not performed (4 in group A, 1 in group N). Therefore, 163 tracheal insertion attempts were performed, 80 in group A and 83 in group N.

The median device insertion time was less than 20 seconds for both groups using both automated and manual modes (Figure 3). In manual mode, group A had a median time of 17.0 s (IQR 11.6-26.0 s, range [3.8-132.1 s]) comparable to group N with a median time of 18.1 s (IQR 12.8-21.1 s, range [7.6-133 s]). In automated mode, group A had a median time of 15.0 s (IQR 12.9-18.1 s, range [7.0-25.2 s]) comparable to group N with a median time of 15.9 s (IQR 13.2-22.8 s, range [9.7-58.3 s]). In the mixed linear model, group A performed faster using the automated mode compared to the manual mode (95% CI from 2.7 to 17.6 seconds, p= 0.008). In contrast, no such difference was found in group N (p=0.65).

Both groups demonstrated an effect of increasing experience in the manual mode. The stratified linear mixed model incorporating the order of the intubation attempt as covariate showed strong evidence for an effect of practise: with each attempt, the device insertion occurred on average 5.8 seconds faster in group A (95% CI 2.6 seconds to 9.0 seconds, p<0.001) and 5.1 seconds faster in group N (95% CI 2.1 seconds to 8.3 seconds, p=0.002).

In contrast, there was no improvement over time in the automated mode for either group. The median (IQR [range]) from the first automated insertion round was in Group A 13.6 (11.7-17.7 [7.0-22.0]) seconds, while in the 6th round resulted the median (IQR [range]) was 15.2 (14.7-15.8 [14.3-20.9]) seconds. In Group N, the median (IQR [range]) of the first round was 16.5 (15.1 to 27.1 [12.6-39.4]) seconds and the median (IQR [range]) of the 6th round 20.2 (14.0-21.3 [12.8-37.6]) seconds. This descriptive information was confirmed in the model for the automated mode (p-values 0.99 in group N and 0.30 in group A).

Using a Likert scale from 0 (very difficult) to 10 (very easy), "ease of handling" resulted in a mean score and standard deviation of 5.9 ± 2.1 in Group A and 6.9 ± 1.3 in Group N (p = 0.51).

Discussion

The objective of this study was to assess the success rate and ease of use of the REALITI device for insertion into the trachea of an airway manikin. The study was designed to distinguish the performance of both experienced and naïve airway managers in both manual and automated modes using the REALITI system. We did not ask the participants to perform complete tracheal intubations by sliding a tracheal tube into the airway, in order to study the REALITI device without potential confounding.

Tracheal intubation is often not performed by paramedics due to local or national restrictions or lack of experience or maintenance of skills of the involved medical personnel. [2,3,6,7] The ultimate goal of our REALITI project is to expand patient care by enabling healthcare providers, who might infrequently perform tracheal intubation to do so with the aid of anatomic recognition and steering technology. An automated system that enables device insertion into the trachea may contribute to a change in the regulations by expanding the spectrum of users, as it happened with the spread of automated external defibrillators (AED) [9].

In this study, participants in both A and N groups quickly familiarised themselves with the REALITIT device. Both groups showed a training effect with comparatively little practise.

A significant limitation of this study is the small number of participants, therefore any conclusions regarding comparative performance are underpowered. In addition, this is a proof-of-concept manikin trial and the reduction of the airway management to inserting the endoscope without placing a tracheal tube, is a simplification of the procedure. The novelty lies in the successful application of image recognition of anatomical airway features and the translation of the recognized structures into an automated steering of the endoscope tip into the trachea, which was programmed for this manikin. The addition of a tracheal tube to this procedure and applications in humans will occur in future studies.

In conclusion, we have performed successful computer-assisted manikin tracheal insertions of the REALITI device that may lead to tracheal intubation by less experienced healthcare personnel. Our study shows that novice users are able to quickly acquire the skillset to place the device in a manikin's airway in a time similar to that of experienced anaesthesia providers.

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References

1. Apfelbaum JL, Hagberg CA, Caplan RA, Blitt CD, Connis RT, Nickinovich DG, Hagberg CA, Caplan RA, Benumof JL, Berry FA, Blitt CD, Bode RH, Cheney FW, Connis RT, Guidry OF, Nickinovich DG, Ovassapian A, American Society of Anesthesiologists Task Force on Management of the Difficult A. Practice guidelines for management of the difficult airway: an updated report by the American Society of Anesthesiologists Task Force on Management of the Difficult Airway. *Anesthesiology* 2013- **118**: 251-70.

2. Bair AE, Smith D, Lichty L. Intubation confirmation techniques associated with unrecognized non-tracheal intubations by pre-hospital providers. *Journal of Emergency Medicine* 2005- **28**: 403-7.

3. Carlson JN, Das S, De la Torre F, Frisch A, Guyette FX, Hodgins JK, Yealy DM. A Novel Artificial Intelligence System for Endotracheal Intubation. *Prehospital Emergency Care* 2016- **20**: 667-71.

4. Goldberg SA, Leatham A, Pepe PE. Year in review 2012: Critical Care--Out-of-hospital cardiac arrest and trauma. *Critical Care* 2013- **17**: 248.

5. Myers LA, Gallet CG, Kolb LJ, Lohse CM, Russi CS. Determinants of Success and Failure in Prehospital Endotracheal Intubation. *Western Journal of Emergency Medicine* 2016- **17**: 640-7.

6. Goto T, Watase H, Morita H, Nagai H, Brown CA, 3rd, Brown DF, Hasegawa K, Japanese Emergency Medicine Network I. Repeated attempts at tracheal intubation by a single intubator associated with decreased success rates in emergency departments: an analysis of a multicentre prospective observational study. *Emerg Med J* 2015- **32**: 781-6.

7. Liu DX, Ye Y, Zhu YH, Li J, He HY, Dong L, Zhu ZQ. Intubation of non-difficult airways using video laryngoscope versus direct laryngoscope: a randomized, parallel-group study. *BMC Anesthesiol*ogy 2019- **19**: 75.

8. Hubble MW, Brown L, Wilfong DA, Hertelendy A, Benner RW, Richards ME. A meta-analysis of prehospital airway control techniques part I: orotracheal and nasotracheal intubation success rates. *Prehospital Emergency Care* 2010- **14**: 377-401.

9. Malta Hansen C, Rosenkranz SM, Folke F, Zinckernagel L, Tjornhoj-Thomsen T, Torp-Pedersen C, Sondergaard KB, Nichol G, Hulvej Rod M. Lay Bystanders' Perspectives on What Facilitates Cardiopulmonary Resuscitation and Use of Automated External Defibrillators in Real Cardiac Arrests. *Journal of the American Heart Association* 2017- **6**: e004572. DOI: 10.1161/JAHA.116.

Table 1. Demographic characteristics. Values are displayed as numerals or median [range] where applicable.

Characteristics	**Group A (n = 7)**	**Group N (n = 7)**
Age (y [range])	40 [25 - 41]	28 [23 - 30]
Gender (f : m)	4 : 3	1 : 6
Intubation experience (n [range])	750 [100 - 1000]	0 [0]
Flexible endoscope intubation experience (yes : no)	4 : 3	0 : 7
Joystick experience (yes : no)	4 : 3	5 : 2

Figures

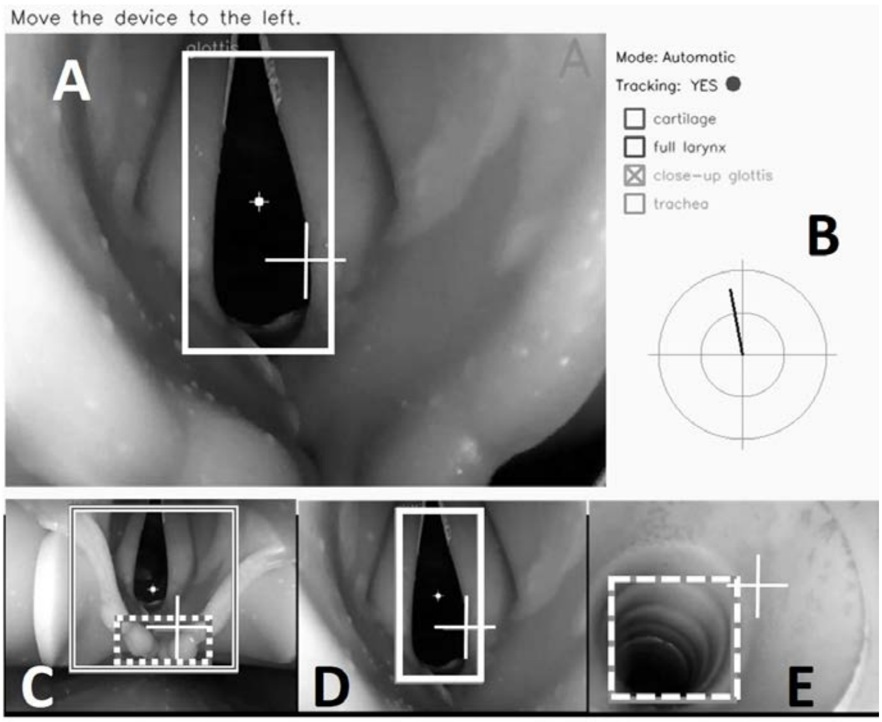

Figure 1. User interface and anatomical features detection. The square indicates the successful recognition of the laryngeal inlet. The white dot represents the detected entrance of the glottis, while the white cross aims into the direction the tip is pointing. This difference triggers the proposal to "move the device to the left", which has appeared in the left upper corner of the screen. The entire larynx (double line square), the corniculate cartilages (dotted small square), glottis (full line square), and subglottic trachea (segmented square). On the video screen, these squares are colour coded for better differentiation.

Figure 2. Study setup: the intubation manikin and the video monitor displaying the tip camera view and steering information.

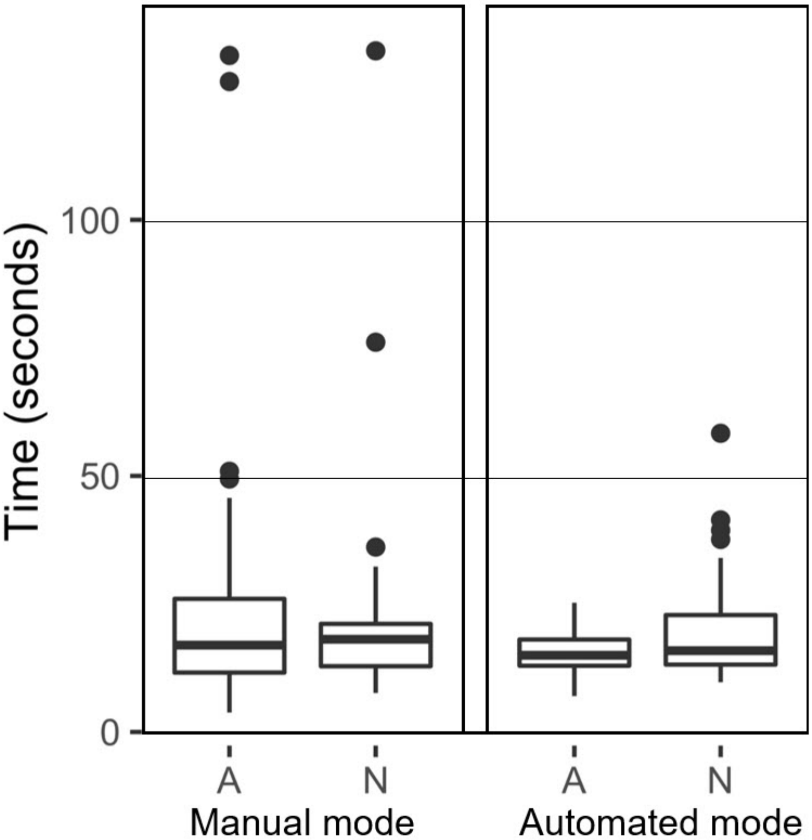

Figure 3. Boxplots of times to device insertion by mode and group. Black dots denote outliers, defined as being more than 1.5 times the interquartile range away from the hinges of the boxes.